

Atlanta VA Health Care System Consent Guidance for COVID-19 Research Subjects

Unless waived by an IRB, informed consent and HIPAA authorization must be obtained from the subject or the subject's legally authorized representative. One cannot make informed consent optional when required by the IRB because the prospective subject is in COVID-19 isolation. The method used to obtain consent should be described in an IRB submission or amendment and requires IRB approval. Examples of approved consenting options for subject's in isolation are listed below.

1. Obtaining consent from alert and oriented subject

A. Scenario when photocopy of signature page(s) is obtained

- i. Provide subject with ICF/HIPAA and pen. You may ask a healthcare worker who is going into the room for other purposes, to give the forms to the subject.
- ii. Conduct the informed consent process either via phone, video, or in-person.
- iii. Don appropriate PPE if entering room. Ask patient to wear mask when appropriate.
- iv. Subject signs the combined or separated ICF and HIPAA.
- v. Person obtaining consent (POC) signs the ICF.
 - If POC in the room, they can sign the ICF signed by subject.
 - If POC is not in the room, they sign separate clean document(s). There will be two sets of documents in this case. One the subject signed and one the POC signed.
- vi. POC, subject, or healthcare worker takes picture of subject's signed signature page(s) using cellphone and sends to study team.
- vii. Print photo for your research records.
- viii. Leave ICF/HIPAA in subject's room due to possible contamination.
- ix. No need for witnesses in this scenario.
- x. Document the consent process in detail as outlined above.

B. Scenario when photocopy of signature page(s) is **not** obtained

- i. Have healthcare worker give ICF, HIPAA, and pen to subject.
- ii. Arrange 3-way call or video with:
 - Subject
 - Two impartial witnesses present during call (two needed for HIPAA)
 - Include family member(s) or others if desired by subject
 - Set up VANTS line if needed. Call (304) 262-7600.
- iii. During call:
 - Identify who is on the call
 - Review the consent/HIPAA with subject and answer questions
 - One witness needs to verbally confirm that subject's questions were answered
 - The investigator or POC needs to verbally confirm that the subject is willing to participate in the trial and has signed the consent/HIPAA while the witness is listening on the phone.

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- Subject needs to verbally confirm that they would like to participate in the trial, that they have signed and dated the ICF/HIPAA and verify the version and/or approval dates of the ICF/HIPAA.
 - iv. The ICF/HIPAA will not be retrieved due to possible contamination.
 - v. ICF: The POC and 1 witness need to sign a clean ICF.
 - vi. HIPAA: Both witnesses need to sign, date, and list their title on the signature page of the HIPAA authorization. If the HIPAA is combined with the ICF, enter signature, date, and title on the ICF signature page.
 - vii. POC must document the above consent process and details either in CPRS or on paper source. State ICF/HIPAA not retained d/t possible contamination by infectious material, how consent was obtained, and the other details listed above.
 - viii. Place ICF/HIPAA with research records.
2. If Legally Authorized Representative (LAR) signing on behalf of subject. This is only permitted when subject is not competent.
- A. 3-way phone call or video conference
- i. Follow all the steps outlined above in section 1.B.
 - ii. Document LAR name, number, and relationship
 - iii. If LAR is the Power of Attorney (POA) or Court Appointed Legal Guardian, they are permitted to sign HIPAA on behalf of the subject.
 - iv. If LAR is not a POA or Court Appointed Legal Guardian, the study must have a full HIPAA waiver in place for this circumstance. DO NOT HAVE a LAR who is not a POA or Court Appointed Legal Guardian SIGN THE HIPAA. Leave it blank. This is allowed when there is a full HIPAA waiver.
 - v. When possible, have LAR fax, email, or take a picture of signature page and send to study team. CSC Fax: 404 417-1518